IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA	§	
	§	
v.	§	Criminal No. 3:15-CR-496-L
	§	
USPLABS, LLC (01)	§	
JACOBO GEISSLER (02)	§	
JONATHAN DOYLE (03)	§	
MATTHEW HEBERT (04)	§	
KENNETH MILES (05)	§	
S.K. LABORATORIES, INC. (06)	§	
SITESH PATEL (07)	§	
CYRIL WILLSON (08)	§	

MEMORANDUM OPINION AND ORDER

Before the court are Defendants' Objection to the Magistrate Judge's Order with Respect to Defendants' Motion to Exclude Expert Testimony by Drs. Gurley, Koturbash, and Boerma (Doc. 481), filed June 25, 2018; Defendants' Objection to Magistrate Judge's Order with Respect to Defendants' Motions to Exclude Expert Testimony by Drs. ElSohly and Oberlies (Doc. 484), filed June 25, 2018; and Defendants' Joint Objection to the Magistrate Judge's Order Denying Defendants' Motion to Exclude the Proposed Expert Testimony of Dr. Herbert Bonkovsky (Doc. 557) (under seal), filed June 25, 2018.

Having carefully considered United States Magistrate Judge Renée Harris Toliver's Order dated June 8, 2018 (Doc. 474), the transcript of her May 8, 2018 hearing (Doc. 479-12), Defendants' objections (Docs. 481, 484, and 557), the Government's responses to Defendants' objections (Docs. 498, 501, and 503), record, and applicable law, and for the reasons set forth herein, the court **sustains** Defendants' Objection to the Magistrate Judge's Order with Respect to Defendants' Motion to Exclude Expert Testimony by Drs. Gurley, Koturbash, and Boerma (Doc. 481); **overrules**

Defendants' Objection to Magistrate Judge's Order with Respect to Defendants' Motions to Exclude Expert Testimony by Drs. ElSohly and Oberlies (Doc. 484); and **overrules** Defendants' Joint Objection to the Magistrate Judge's Order Denying Defendants' Motion to Exclude the Proposed Expert Testimony of Dr. Herbert Bonkovsky (Doc. 557).

I. Factual Background

A. The Defendants

Defendants are USPlabs, LLC ("USPlabs"), a dietary supplement own-label distributor based in Dallas, Texas; S.K. Laboratories, Inc. ("S.K. Labs"), a California corporation that manufactured USPlabs' supplements and consulted on supplement formulation; Jacobo Geissler ("Geissler"), a co-founder, co-owner, and chief executive officer of USPlabs; Jonathan Doyle ("Doyle"), a co-founder, co-owner, and president of USPlabs; Matthew Hebert ("Hebert"), a co-owner of USPlabs and responsible for product packaging design; CyrilWillson ("Willson"), also known as "Erik White," a consultant to USPlabs, formerly a co-owner; Kenneth Miles ("Miles"), USPlabs' compliance officer; and Sitesh Patel ("Patel"), a vice-president and employee of S.K. Labs (collectively, "Defendants," unless otherwise qualified).

B. The Indictment

On January 5, 2016, the Government filed an 11-Count Superseding Indictment ("the Indictment") (Doc. 95) against Defendants. The charges in the Indictment stem from Defendant USPlabs' sale of dietary/weight loss supplements, which were manufactured by Defendant S.K. Labs. Doc. 95 at 5-6. The Indictment generally alleges that Defendants conspired to import and sell synthetic dietary supplements but falsely marketed the products as plant-based under the theory that federal regulatory agencies would be less likely to question the importation of plant extracts, and

retailers would be more likely to sell such products. Doc. 95 at 6. The Indictment further alleges that, during the conspiracy, certain Defendants created false documentation to import a synthetic substance—1,3-dimethylamylamine, known as DMAA—that they represented was a geranium plant extract. According to the Indictment, certain Defendants then used the DMAA in some of their supplements, which thereafter became best-selling products. Doc. 95 at 7, 14-15.

It is further alleged that when DMAA became the subject of controversy in the dietary supplement industry, USPlabs, through Defendant Geissler, began importing other chemicals under false labels to determine if they could be used in new dietary supplements. Doc. 95 at 9. Two such ingredients were aegeline, a synthetic version of an extract from a tree native to India, and the pulverized roots of a Chinese herb, cynanchum auriculatum ("CA"), both of which USPlabs is alleged to have purchased from China using fake certificates of analysis ("COA").[1] The first aegeline-containing version of one of Defendants' supplements was OxyElite Pro "New Formula" ("OEP-NF"). Doc. 95 at 9-10. The second version of the supplement contained both aegeline and CA and was called OxyElite Pro "Advanced Formula" ("OEP-AF"). Doc. 95 at 10.

As alleged in the Indictment, in the fall of 2013, an outbreak of injuries was reported to be associated with USPlabs' aegeline-based products after numerous consumers in Hawaii experienced liver-related symptoms, including liver failure. Doc. 95 at 11. Following an inspection by the United States Food and Drug Administration ("FDA"), USPlabs agreed to cease distributing the OEP products but is alleged to have instead pushed sales as fast as possible. Doc. 95 at 11. The

[1] The Food and Drug Administration ("FDA") defines a COA as "a document, provided by the supplier of a component prior to or upon receipt of the component, that documents certain characteristics and attributes of the component." Guidance for Industry Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 2010 WL 5574459, at *9 (Dec. 1, 2010).

Indictment also alleges that USPlabs issued a press release falsely stating that the ingredients in OEP had been researched and showed no negative liver effects, even though Defendants Geissler and Willson knew that a study had shown such negative side effects. Doc. 95 at 11. Eventually, Geissler instructed that both aegeline and CA be removed from the product going forward. Doc. 95 at 11.

The Indictment contains the following charges[2]:

Count 1 – *Conspiracy to Commit Wire Fraud* (as to all Defendants except Miles), 18 U.S.C. §§ 1343, 1349; Doc. 95 at 12-17. This count involves Defendants' alleged use of false shipping labels, false COAs, and false shipping documentation to support misleading product labeling in relation to statements that the respective supplements contained "natural" DMAA derived from geranium and CA "extract" (as opposed to CA "root").

Counts 2-5 – *Wire Fraud*, 18 U.S.C. § 1343 (as to all Defendants except Miles); Doc. 95 at 18-19. These counts involve Defendants' alleged transmission in interstate commerce, by means of wire communications and writing, of false and fraudulent COAs, instructions to create false documents, and other fraudulent statements contained in e-mails.

Count 6 – *Obstruction of an Agency Proceeding* (as to Defendants USPlabs, Geissler, Doyle, and Hebert only), 18 U.S.C. §§ 2, 1505; Doc. 95 at 20-21. This count charges that, during the FDA investigation regarding whether an outbreak of liver injuries was associated with USPlabs' products containing aegeline, Defendants USPlabs, Geissler, Doyle, and Hebert continued to distribute OEP products despite representing to the FDA that they would cease distribution, and attempted to impede the FDA's investigation by failing to provide material information about OEP, the anticipated shipments of OEP, and promotional activities for OEP.

Count 7 – *Conspiracy to Introduce Misbranded Food into Interstate Commerce with an Intent to Defraud and Mislead*, 18 U.S.C. § 371; 21 U.S.C. §§ 331(a), 333(a)(2) (as to all Defendants except Miles); Doc. 95 at 22-24. This count alleges that certain Defendants conspired to avoid law enforcement attention and match imported substances with false product labeling by instructing Chinese chemical sellers to falsely label numerous chemical powders they sent to USP, including "geranium flower powder extract" and CA root "extract."

[2] The Indictment spells out the number of each count rather than using Arabic numerals, for example, "Count One," instead of "Count 1." The parties sometimes refer to the counts with Arabic numerals and other times spell out the number of each count. For purposes of consistency, the court will use Arabic numerals when referring to the counts in the Indictment, except when quoting the exact title of a motion.

Count 8 – *Introduction of Adulterated Food into Interstate Commerce with an Intent to Defraud and Mislead* (as to Defendants USPlabs and Geissler only), 21 U.S.C. §§ 331(a), 333(a)(2); 18 U.S.C. § 2; Doc. 95 at 25. This count alleges that Defendants USPlabs and Geissler, aiding and abetting each other, with the intent to defraud and mislead, caused the shipment of misbranded OEP-AF in interstate commerce by using a label falsely declaring that CA "extract" was an ingredient, even though it was not contained in the product.

Count 9 – *Introduction of Misbranded Food into Interstate Commerce* (as to Defendants Doyle, Hebert, Miles, S.K. Labs, and Patel only), 21 U.S.C. §§ 331(a), 333(a)(2); Doc. 95 at 26. This count alleges that Defendants Doyle, Hebert, Miles, S.K. Labs, and Patel caused the shipment of misbranded OEP-AF in interstate commerce when the food was misbranded under the Food Drug and Cosmetic Act ("FDCA") by using a false label declaring that CA "extract" was an ingredient, even though it was not contained in the product.

Count 10 – *Introduction of Adulterated Dietary Supplement into Interstate Commerce*, 21 U.S.C. §§ 331(a), 333(a)(1), and 342(f)(1)(A)(I) (as to all Defendants except Willson); Doc 95 at 27. This count alleges that Defendants caused the shipment of adulterated OEP-NF in interstate commerce, as the supplement "presented a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling."

Count 11 - *Conspiracy to Commit Money Laundering* (as to Defendants USPlabs, Geissler, Doyle, and Hebert only), 18 U.S.C. § 1956(h); Doc. 95 at 28-29. This count alleges that Defendants USPlabs, Geissler, Doyle, and Hebert conspired to transfer over $230,000,000 of proceeds obtained through wire fraud and conspiracy in a manner designed to conceal the true source and nature of the criminally derived funds.

With respect to ruling on Defendants' objections, much of the proffered expert testimony relates to Count 10 of the 11-Count Indictment. Count 10—*Introduction of Adulterated Dietary Supplement into Interstate Commerce*—alleges that Defendants (except Willson) caused the shipment of adulterated OEP-NF in interstate commerce, knowing the supplement "presented a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling." Doc 95 at 27 (citing 21 U.S.C. §§ 331(a), 333(a)(1), and 342(f)(1)(A)(I)).

In support of the allegations in the Indictment, on May 1, 2017, the Government designated the following eight experts to testify at trial: Herbert L. Bonkovsky, M.D. ("Dr. Bonkovsky"); Karl C. Klontz, M.D. ("Dr. Klontz"); Nicholas H. Oberlies, Ph.D. ("Dr. Oberlies"); Bill J. Gurley, Ph.D. ("Dr. Gurley"); Igor Koturbash, M.D., Ph.D. ("Dr. Koturbash"); Marjan Boerma, Ph.D. ("Dr. Boerma"); Mahmoud ElSohly, Ph.D. ("Dr. ElSohly"); and Catherine D. Tucker. Gov't's Notice of Testimony under Fed. Rules of Evid. Rules 702, 703, and 705 (Doc. 222) ("Gov't's Notice of Expert Testimony"). On June 1, 2017, Defendants moved to exclude all eight of the Government's designated experts.

In support of their defense to the charges in the Indictment, on June 8, 2017, Defendants designated the following 13 experts to testify at trial: Christopher J. Borgert, Ph.D. ("Dr. Borgert"); M. Eric Gershwin, M.D. ("Dr. Gershwin"); Robert D. Gibbons, Ph.D. ("Dr. Gibbons"); Hartmut Jaeschke, Ph.D., ATS ("Dr. Jaeschke"); Judith K. Jones, M.D., Ph.D. ("Dr. Jones"); Haavi Morreim, Ph.D., J.D. ("Dr. Morreim"); Joseph Rodricks, Ph.D., DABT ("Dr. Rodricks"); Paul S. Simone, Jr., Ph.D. ("Dr. Simone"); William J. Brock, Ph.D., DABT, Fellow ATS ("Dr. Brock"); Kirk L. Barnes; Robert G. Gish, M.D. ("Dr. Gish"); Stephen Scheets, CPA; and James Lassiter. Defs.' Notice of Expert Testimony (Doc. 232). On June 8, 2017, the Government moved to exclude seven of Defendants' experts pursuant to Federal Rule of Evidence 702, namely, Drs. Borgert, Gershwin, Gibbons, Jaeschke, Jones, Morreim, and Simone. In addition, contending that Defendants failed to comply with the expert disclosure requirements set forth in Federal Rule of Criminal Procedure 16(b)(1)(C), the Government moved to exclude the expert testimony of Kirk Barnes, James Lassiter, Stephen Scheets, and Drs. Brock and Gish, and a portion of the testimony of Dr. Rodricks.

C. Referral to Magistrate Judge Toliver for Determination

Pursuant to 28 U.S.C. § 636(b)(1)(A) and Federal Rule of Criminal Procedure 59(a), the court referred the nondispositive motions to Magistrate Judge Toliver for hearing, if necessary, and determination:

> Defendants' Motion to Exclude Expert Testimony by Catherine D. Tucker (Doc. 251);
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> Defendants' Motion to Exclude Expert Testimony by Nicholas Oberlies, Ph.D. (Doc. 252);
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> Defendants' Motion to Exclude Expert Testimony by Drs. Gurley, Koturbash, and Boerma (Doc. 253);
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> Defendants' Joint Motion to Exclude the Expert Testimony of Dr. Mahmoud ElSohly (Doc. 256);
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> Government's Motion to Preclude Proposed Defense Expert Christopher Borgert (Doc. 259);
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> Government's Motion to Exclude Proposed Defense Expert Eric Gershwin (Doc. 260);
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> Government's Motion to Preclude Proposed Defense Expert Robert Gibbons (Doc. 261);
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> Government's Motion to Preclude Proposed Defense Expert Hartmul Jaeschke (Doc. 262);
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> Government's Motion to Preclude Proposed Defense Expert Judith Jones (Doc. 263);
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> Government's Motion to Preclude Proposed Defense Expert Haavi Morreim (Doc. 264);
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> Government's Motion to Exclude Portions of Joseph Rodricks' Proposed Testimony for Failure to Comply With Fed. R. Crim.P. 16(b)(1)(C) (Doc. 265);
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> Government's Motion to Preclude Proposed Defense Expert Paul Simone (Doc. 266);
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> Government's Motion to Exclude Five Proposed Defense Experts for Failure to Comply With Fed. R. Crim. P. 16(b)(1)(C) (Doc. 267);

Defendants' Sealed Motion to Exclude Dr. Herbert Bonkovsky's Testimony (Doc. 277); and

Defendants' Sealed Motion to Exclude the Testimony of Dr. Karl Klontz, M.D. (Doc 278).

See Order of Reference (Doc. 343).

On May 9, 2018, after the motions were fully briefed, Magistrate Judge Toliver held a hearing on the referred motions. On June 8, 2018, she issued an 84-page Order:

• granting Defendants' Motion to Exclude Expert Testimony by Catherine D. Tucker (Doc. 251);

• denying in part and granting in part Defendants' Motion to Exclude Expert Testimony by Nicholas Oberlies, Ph.D. (Doc. 252);

• denying in part and granting in part Defendants' Motion to Exclude Expert Testimony by Drs. Gurley, Koturbash, and Boerma (Doc. 253);

• denying Defendants' Joint Motion to Exclude the Expert Testimony of Dr. Mahmoud Elsohly (Doc. 256);

• denying the Government's Motion to Preclude Proposed Defense Expert Christopher Borgert (Doc. 259);

• denying the Government's Motion to Exclude Proposed Defense Expert Eric Gershwin (Doc. 260);

• denying the Government's Motion to Preclude Proposed Defense Expert Robert Gibbons (Doc. 261);

• denying the Government's Motion to Preclude Proposed Defense Expert Hartmul Jaeschke (Doc. 262);

• denying the Government's Motion to Preclude Proposed Defense Expert Judith Jones (Doc. 263);

• denying the Government's Motion to Preclude Proposed Defense Expert Haavi Morreim (Doc. 264);

• denying the Government's Motion to Exclude Portions of Joseph Rodricks' Proposed Testimony for Failure to Comply With Fed. R. Crim. P. 16(b)(1)(C) (Doc. 265);

• denying the Government's Motion to Preclude Proposed Defense Expert Paul Simone (Doc. 266);

• denying the Government's Motion to Exclude Five Proposed Defense Experts for Failure to Comply With Fed. R. Crim. P. 16(b)(1)(C) (Doc. 267);

• denying Defendants' Sealed Motion to Exclude Dr. Herbert Bonkovsky's Testimony (Doc. 277); and

• granting Defendants' Sealed Motion to Exclude the Testimony of Dr. Karl Klontz, M.D. (Doc 278).

Order 83-84 (Doc. 474).[3]

D. Objections

On June 25, 2018, Defendants filed the following objections to her Order:

Defendants' Objection to the Magistrate Judge's Order with Respect to Defendants' Motion to Exclude Expert Testimony by Drs. Gurley, Koturbash, and Boerma (Doc. 481);

Defendants' Objection to Magistrate Judge's Order with Respect to Defendants' Motions to Exclude Expert Testimony by Drs. ElSohly and Oberlies (Doc. 484); and

Defendants' Joint Objection to the Magistrate Judge's Order Denying Defendants' Motion to Exclude the Proposed Expert Testimony of Dr. Herbert Bonkovsky (Doc. 557) (under seal).

On July 16, 2018, the Government filed its responses to Defendants' objections, contending that Magistrate Judge Toliver's rulings were correct and asking the court to overrule Defendants'

[3] Although denying the Government's motions to exclude certain expert testimony for failure to comply with the disclosure requirements in Federal Rule of Criminal Procedure 16(b)(1)(C), Magistrate Judge Toliver ordered Defendants to supplement the expert testimony of Drs. Borgert, Brock, Jaeschke, and Rodricks with respect to certain aspects of their expected testimony. *See* Order 52, 63, 74, 78. On July 2, 2018, in compliance with her Order, Defendants filed their Joint Supplemental Notice of Expert Testimony (Doc. 489) and Exhibits thereto (Docs. 489-1 and 489-2).

objections. *See* Docs. 498, 501, 503. The Government filed no objections to Magistrate Judge Toliver's Order.

II. Legal Standards

A. Standard of Review

Pursuant to Federal Rule of Criminal Procedure 59(a) and 28 U.S.C. § 636(b)(1)(A), a district court, on its own motion, may refer a pending nondispositive matter to a United States Magistrate Judge for determination. Fed. R. Crim. P. 59(a); 28 U.S.C. § 636(b)(1)(A). The non-prevailing party may contest the magistrate judge's determination by filing written objections within fourteen days of being served with a copy of the order. Fed. R. Crim. P. 59(a). The standard of review for a decision of a magistrate judge in a nondispositive matter is governed by Rule 59(a), which provides that the district judge "must consider timely objections and modify or set aside any part of the order that is contrary to law or clearly erroneous." *Id.*; *see also* 28 U.S.C. § 636(b)(1)(A) ("A judge of the court may reconsider any [nondispositive] pretrial matter . . . where it has been shown that the magistrate's order is clearly erroneous or contrary to law.").

This highly deferential standard requires the court to affirm the decision of the magistrate judge unless "on the entire evidence [the court] is left with a definite and firm conviction that a mistake has been committed." *Baylor Health Care Sys. v. Equitable Plan Servs., Inc.*, 955 F. Supp. 2d 678, 689 (N.D. Tex. 2013) (Lindsay, J.) (quoting *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948)). As explained by anther district court in this Division:

> The clearly erroneous standard applies to the factual components of the magistrate judge's decision. The district court may not disturb a factual finding of the magistrate judge unless, although there is evidence to support it, the reviewing court is left with the definite and firm conviction that a mistake has been committed. If a magistrate judge's account of the evidence is plausible in light of the record viewed in its entirety, a district judge may not reverse it. The legal conclusions of the magistrate

> judge are reviewable de novo, and the district judge reverses if the magistrate judge erred in some respect in [his] legal conclusions. [T]he abuse of discretion standard governs review of that vast area of choice that remains to the [magistrate judge] who has properly applied the law to fact findings that are not clearly erroneous.

Arters v. Univision Radio Broadcasting TX, L.P., 2009 WL 1313285, at *2 (N.D. Tex. May 12, 2009) (Fitzwater, C.J.)) (citations and internal quotations marks omitted).

A party's failure to file written objections to the magistrate judge's order within fourteen days shall bar that party from review by a district court. Fed. R. Crim. P. 59(a). As Defendants have filed their objections in a timely manner, the court will review the portions of Magistrate Judge Toliver's Order to which they have objected.

B. Federal Rule of Evidence 702 and Admissibility of Expert Testimony

The admissibility of evidence is a procedural issue governed by federal law. *See Reed v. General Motors Corp.*, 773 F.2d 660, 663 (5th Cir. 1985). Rule 702 governs the admissibility of expert testimony and provides that:

> [a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

The trial court acts as a "gatekeeper" to ensure that "any and all scientific evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). "*Daubert*'s general holding—setting forth the trial judge's general 'gatekeeping' obligation—applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

In its gatekeeping role, the court determines the admissibility of expert testimony based on Rule 702 and *Daubert* and its progeny. "The court may admit proffered expert testimony only if the proponent, who bears the burden of proof, demonstrates that (1) the expert is qualified, (2) the evidence is relevant to the suit, and (3) the evidence is reliable." *E.E.O.C. v. S&B Indus., Inc.*, 2017 WL 345641, at *2 (N.D. Tex. Jan. 24, 2017) (Fitzwater, J.) (internal quotation marks omitted) (citing *Kumho Tire Co.*, 526 U.S. at 147).

To be relevant, "expert testimony [must] 'assist the trier of fact to understand the evidence or to determine a fact in issue.'" *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 245 (5th Cir. 2002) (quoting *Daubert*, 509 U.S. at 591). "Relevance depends upon 'whether [the expert's] reasoning or methodology properly can be applied to the facts in issue.'" *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 352 (5th Cir. 2007) (quoting *Daubert*, 509 U.S. at 593); *see also* Fed. R. Evid. 702(d) (requiring that an "expert has reliably applied the principles and methods to the facts of the case").

"Reliability is determined by assessing 'whether the reasoning or methodology underlying the testimony is scientifically valid.'" *Knight*, 482 F.3d at 352 (quoting *Daubert*, 509 U.S. at 592-93); *see also* Fed. R. Evid. 702(c) (requiring that "testimony [be] the product of reliable principles and methods"). "The reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the

conclusion, et alia." *Knight*, 482 F.3d at 355. "The reliability prong mandates that expert opinion be grounded in the methods and procedures of science and . . . be more than unsupported speculation or subjective belief." *Johnson v. Arkema, Inc.*, 685 F.3d 452, 459 (5th Cir. 2012) (internal quotation marks omitted). "[T]here is no requirement that an expert derive his opinion from firsthand knowledge or observation." *Deshotel v. Wal-Mart La., L.L.C.*, 850 F.3d 742, 746 (5th Cir. 2017) (internal quotation marks omitted).

"The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. "The proponent need not prove to the judge that the expert's testimony is correct, but she must prove by a preponderance of the evidence that the testimony is reliable." *Johnson*, 685 F.3d at 459 (internal quotation marks omitted). If "there is simply too great an analytical gap between the [basis for the expert opinion] and the opinion proffered," the court may exclude the testimony as unreliable. *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

Courts consider the following non-exclusive list of factors when conducting the reliability inquiry:

> (1) whether the theory or technique has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error of the method used and the existence and maintenance of standards controlling the technique's operation; and (4) whether the theory or method has been generally accepted by the scientific community.

Johnson, 685 F.3d at 459 (internal quotation marks omitted).

The burden is on the proponent of the expert testimony to establish its admissibility by a preponderance of the evidence. *See Daubert*, 509 U.S. at 592 n.10; *see also Johnson*, 685 F.3d at 459. The court's inquiry is flexible in that "[t]he relevance and reliability of expert testimony turns

upon its nature and the purpose for which its proponent offers it." *United States v. Valencia*, 600 F.3d 389, 424 (5th Cir. 2010) (citation omitted). "As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the [trier of fact's] consideration." *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 422 (5th Cir. 1987). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

III. Analysis

A. Defendants' Objection to the Magistrate Judge's Order with Respect to Defendants' Motion to Exclude Expert Testimony by Drs. Gurley, Koturbash, and Boerma (Doc. 481)[4]

1. Drs. Gurley and Koturbash

Prior to addressing Magistrate Judge Toliver's denial of Defendants' motion to exclude the expert testimony of Drs. Gurley and Koturbash, and Defendants' specific objections to her rulings, a brief understanding of the anticipated expert testimony of Drs. Gurley and Koturbash is needed to provide context to Magistrate Judge Toliver's ruling and Defendants' objection. The Government designated University of Arkansas professors Drs. Gurley and Koturbash to testify that OEP-NF—the USPlabs product the Government contends was adulterated in Count 10 of the

[4] Although Defendants style their objection as a challenge to Magistrate Judge Toliver's Order pertaining the testimony of Drs. Gurley, Koturbash, *and* Boerma, she granted their motion to exclude Dr. Boerma's testimony as irrelevant. Specifically, she agreed with Defendants that Dr. Boerma's testimony that OEP-NF caused decreased cardiac output in mice was irrelevant because, among other things, the Indictment does not allege that users of OEP-NF suffered any cardiac-related injuries. Instead, the allegations set forth in the Indictment focus only on the "hepatotoxicity of the supplements at issue, not their effect on the heart." Order 41 (Doc. 474). As such, notwithstanding the title of their motion, the court understands Defendants' objections to be limited to Magistrate Judge Toliver's denial of their motion to exclude Drs. Gurley and Koturbash.

Indictment—had "toxic potential," that "hepatotoxicity cannot be completely ruled out," and that the product is associated with liver "reactivity." *See* Gov't's Notice of Expert Testimony 41-42 (Doc. 222). Drs. Gurley and Koturbash conducted a study of OEP-NF, which proceeded in phases using various strains of mice as test subjects and varying dosages of OEP-NF ("the Mouse Study"). The "acute" phase of the Mouse Study used a mouse-equivalent dosage of 1X as well as three and ten times that dosage (3X and 10X). When the 10X dose proved overly toxic, the doctors eliminated it from the Mouse Study and adopted a dosing range of .5-3X for further studies. Drs. Gurley and Koturbash also assessed the effects of OEP-NF on mice that were fed a diet including the 1X and 3X doses for four and 13 weeks, respectively.

Following the trials and a toxicological evaluation of the mice's livers, the doctors concluded that the "degree and the persistent nature of the observed experimental outcomes, when taken in conjunction with the multiple cellular pathways affected, do not appear to be random and strongly support the conclusion that this product should not be consumed by humans." *Id.* at 33, 39. Drs. Gurley and Koturbash intend to testify that "there is no safe dose of OEP-NF, especially because many people, due to pharmacogenetic differences in pharmacokinetics and pharmacodynamics, will be much more sensitive to the effects of the product than others." *Id.* at 41. Drs. Gurley and Koturbash concluded that OEP-NF poses "a significant risk for producing serious adverse health effects in humans and that these risks far outweigh any potential benefits of OEP-NF," and "no reasonable scientist would permit a substance with this toxicological profile to be given to humans for consumption under any circumstances, let alone sold over the counter to the public as a workout supplement." *Id.* at 42.

Drs. Gurley and Koturbash cite to a number of case reports in the Disclosures, five of which the Government argued supported the conclusions they drew from the Mouse Study, namely, Lauren A. Heidemann et al., "Severe Acute Hepatocellular Injury Attributed to OxyElite Pro: A Case Series," 61 Dig. Diseases Sci., Sept. 2016, at 2741 (Doc. 287-4); Sean Foley et al., "Experience with OxyELITE pro and acute liver injury in active duty service members," 59 Dig. Diseases Sci., Dec. 2014, at 3117 (Doc. 287-5); David I. Johnston et al., "Hepatotoxicity associated with the dietary supplement OxyELITE ProTM — Hawaii, 2013," 8 Drug Testing and Analysis, Mar. 2016, at 319 (Doc. 287-6) (the "Johnston Article"); Marina M. Roytman et al., "Outbreak of Severe Hepatitis Linked to Weight-Loss Supplement OxyELITE Pro," 109 Am J. Gastroenterology, Aug. 2014, at 1296 (Doc. 287-7); and Kevin Chatham-Stephens et al., "Hepatotoxicity associated with weight loss or sports dietary supplements, including OxyELITE ProTM – United States, 2013," 9 Drug Testing and Analysis, Jan. 2016, at 319 (Doc. 287-8) (the "Chatham-Stephens Article").

2. Defendants' Objections to Magistrate Judge Toliver's Denial of Defendants' Motion to Exclude Expert Testimony of Drs. Gurley and Koturbash Concerning Hepatoxity of OEP-NF in Humans Based on Mouse Study

Defendants offer two specific objections to Magistrate Judge Toliver's decision to deny their motion to exclude the expert testimony of Drs. Gurley and Koturbash. First, Defendants argue that Magistrate Judge Toliver "incorrectly applied Fifth Circuit precedent to conclude that Drs. Gurley and Koturbash's Mouse Study was reliable, even though it was not supported by any epidemiological evidence, as the Fifth Circuit clearly requires." Defs.' Obj. 9 (Doc. 481). Second, Defendants argue that Magistrate Judge Toliver "incorrectly concluded that Dr. Gurley's application of the FDA's Guidance for Industry in a way that is the exact opposite of how it was intended to be applied was a reliable methodology." *Id.* In response, the Government argues that "defendants' objection to the

rulings on Drs. Gurley and Koturbash are not really objections to Judge Toliver's findings, but twenty-plus pages of factual disagreements with the government." Gov't's Resp. 3 (Doc. 501). More specifically, the Government contends that (1) assuming it is required to show proximate cause between OEP-NF and liver injuries in humans, "Magistrate Judge Toliver correctly ruled that [Dr. Gurley's and Dr. Koturbash's] opinions are not based solely on the rodent study, but also on a strong scientific consensus in multiple peer-reviewed, published papers that the defendants' product and/or its ingredients are strongly associated with liver injuries" (*id.* at 3-4); and (2) with respect to Defendants' argument pertaining to Dr. Gurley's calculation of animal equivalent dosages based on recommended doses in humans, "Magistrate Judge Toliver reasonably and correctly determined [that Defendants' criticism] goes to the weight of the testimony, not its admissibility" (*id.* at 5). For the reasons that follow, the court will **sustain** Defendants' first objection and, therefore, does not reach their second objection.

a. Summary of Magistrate Judge Toliver's Ruling

In her Order, Magistrate Judge Toliver rejected Defendants' argument that Dr. Gurley's and Dr. Koturbash's conclusions concerning the potential link between OEP-NF and liver injuries in humans were unreliable because they relied solely on the Mouse Study and certain case reports, without any supporting epidemiological studies. Magistrate Judge Toliver began by summarizing the applicable law:

> The Court of Appeals for the Fifth Circuit has noted in the toxic-tort context that "the most useful and conclusive type of evidence . . . is epidemiological studies." *Brock [v. Merrell Dow Pharms., Inc.*, 874 F.2d 307, 313 (5th Cir. 1989), *modified by* 884 F.2d 166 (5th Cir.1989)]. Nevertheless, epidemiologic proof is not a necessary element in all cases, although it is especially suitable "when the only other evidence is in the form of animal studies of questionable applicability to humans." *Id.*; *see also Allen v. Pennsylvania Eng. Corp.*, 102 F.3d 194, 195 (5th Cir. 1996) (upholding the exclusion of expert testimony where no epidemiological study had

> found a statistically significant link between the chemical exposure and human brain cancer, the results of animal studies were inconclusive, and there was no evidence of the level of the decedent's occupational exposure to the chemical in question); *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994) (noting that expert witness was properly excluded when he admitted that no relevant study had been conducted, his hypothesis lacked an empirical foundation, and it had never been subjected to peer review and publication which was "key.").

Order 32 (footnote omitted). Based on this body of case law, Magistrate Judge Toliver rejected Defendants' argument that, under *Brock* and its progeny, the doctors' expert testimony based on the Mouse Study should be excluded under *Daubert* as unreliable, stating:

> In this case, however, the Mouse Study is not the only evidence supporting the experts' opinions about the hepatotoxicity of OEP-NF. Two of the articles upon which Drs. Gurley and Koturbash rely bear the hallmarks of epidemiological studies. The articles, which were both published in the same peer-reviewed journal, report the results of epidemiological outbreak investigations conducted by government personnel following the Hawaii outbreak. *See* Doc. 222 at 45 (citing David I. Johnston et al., "Hepatotoxicity associated with the dietary supplement OxyELITE Pro — Hawaii, 2013," Drug Testing and Analysis, 2016; Kevin Chatham-Stephens et al., "Hepatotoxicity associated with weight loss or sports dietary supplements, including OxyELITE Pro – United States, 2013," Drug Testing and Analysis, 2017).

Id. at 33. Based on her characterization of the Johnston Article and the Chatham-Stephens Article as "bear[ing] the hallmarks of epidemiological studies," Magistrate Judge Toliver concluded:

> *Brock* is thus distinguishable. *See Lofton v. McNeil Consumer & Specialty Pharm.*, No. 05-CV-1531-L(BH), 2008 WL 4878066, at *5 (N.D. Tex. July 25, 2008) (Ramirez, J.) (permitting testimony where the experts relied on published epidemiological studies and case reports and noting that questions about the bases and sources of the opinions affected the weight to be assigned to that opinion rather than its admissibility), *objections overruled* by 682 F. Supp. 2d 662 (N.D. Tex. 2010); *cf. United States v. Bays*, No. 13-CR-357-B, 2014 WL 3764876, *12 (N.D. Tex. July 31, 2014) (Boyle, J.) (permitting the admission of expert testimony even though the expert had relied on unpublished studies and noting that experts may rely on otherwise inadmissible data if experts in their particular field would reasonably do so in forming an opinion); *contra [General Elec. Co. v.] Joiner*, 522 U.S. 136, 144-46 (1997) (upholding the exclusion of testimony where the expert relied on an animal study that was factually dissimilar to the plaintiff's circumstances, two study authors were unwilling to say that chemical exposure had caused a particular type of cancer, a third study did not address the same chemical as in the plaintiff's case, and

> the fourth study involved a group of workers who had been exposed to numerous other potential carcinogens).

Id. at 33-34.[5]

After review of Magistrate Judge Toliver's explanation for denying Defendants' motion to exclude the causation opinions of Drs. Gurley and Koturbash, extensive material submitted, including reference to each of the medical and scientific studies or writings submitted, and Fifth Circuit law, the court concludes that Defendants' objection is well taken. In an exercise of its discretion, and in deference to the gatekeeping role imposed by Rule 702, for the reasons that follow, the court determines that Magistrate Judge Toliver's decision to deny Defendants' motion to exclude the expert testimony of Drs. Gurley and Koturbash concerning the link between OEP-NF and liver injuries in humans was contrary to the law.

b. Discussion

As previously stated, the Fifth Circuit has held that animal studies, standing alone, are of limited usefulness in demonstrating that a chemical agent is toxic to humans, particularly when unaccompanied by evidence of an effect in humans. *Brock*, 874 F.2d at 313. In *Brock*, after outlining a number of reasons why studies of the effects of chemicals on animals must be carefully qualified to have explanatory potential for human beings, the Fifth Circuit found the animal studies, which were introduced to prove that Bendectin is a teratogen, were speculative because of methodological flaws, and the inability to extrapolate the results of those particular studies to humans, based on expert admissions. *Id.* at 313-14. Moreover, the court found that the re-analysis of a study by the plaintiffs' expert on causation was inconclusive as it did not produce a statistical

[5] Magistrate Judge Toliver noted that, following the filing of Defendants' motion to exclude the testimony of Drs. Gurley and Koturbash, "the results of the doctors' Mouse Study were peer reviewed and published in a scientific journal, *Food and Chemical Toxicology*." Order 29 n.13 (Doc. 474).

significance. *Id.* at 313. Lacking any published epidemiologic studies showing a statistically significant effect in humans to support the plaintiffs' underlying theory of causation, the only remaining scientific evidence in *Brock* was the animal studies, which the trial court, and Fifth Circuit in affirming the trial court, found contained methodological flaws. *Id.* at 314-15; *cf. Gulf S. Insulation v. United States Consumer Prod. Safety Comm'n*, 701 F.2d 1137, 1146 (5th Cir.1983) (finding a rat study inconclusive because of the small number of rats tested, the high dosages given to the rats, and difficulty in extrapolating those results to humans).

In *Johnson v. Arkema, Inc.*, 685 F.3d 452 (5th Cir. 2012), relying on *Brock*, the Fifth Circuit again noted the limited usefulness of animal studies standing alone and noted "studies of the effects of chemicals on animals must be *carefully qualified* in order to have explanatory potential for human beings." 685 F.3d at 463 (citing *Allen*, 102 F.3d at 197) (emphasis added). In *Johnson*, the Fifth Circuit upheld the district court's rejection of a baboon study in which experts admitted the baboon's respiratory tract, the affected portion of the body, and human respiratory tract were different, as the human respiratory tract is "pretty unique." *Id.* Moreover, the expert did not attempt to formulate a correlation between the duration and length of baboon exposure and the plaintiff's exposure to the agent that caused the particular malady. *Id.* Finally, the Fifth Circuit noted there were no other animal studies, including other baboon studies, that corroborated the one study at issue's conclusions. *Id.* Therefore, the court concluded under the "careful qualification" requirement that the district court did not abuse its discretion in rejecting the baboon study. *Id.*

Here, Magistrate Judge Toliver determined that this case was distinguishable from cases like *Brock* and *Allen*, and more akin to *Lofton* (permitting testimony when expert relied on case reports and published epidemiological studies), because Drs. Gurley and Koturbash did not rely exclusively

on the Mouse Study to reach their conclusions about the hepatotoxicity of OEP-NF in humans but also on other scholarly articles, two of which she found "bear the hallmarks of epidemiological studies." *See* Order 33. Defendants assert that because none of the five studies was an epidemiological study, her reliance on them, and in particular the Johnston Article and the Chatham-Stephens Article, to bolster the Mouse Study, was clearly erroneous. The court agrees.

The court is mindful of the Fifth Circuit's caution concerning the use of animal studies and its statement that epidemiologic proof, while not a necessary element in all cases, is especially suitable "when the only other evidence is in the form of animal studies of questionable applicability to humans[.]" *Brock*, 874 F.2d at 313. This case, involving expert testimony about a link between OEP-NF and liver injuries in humans based on a rodent study, therefore, is one in which epidemiological proof is especially suitable under *Brock*. The court also recognizes that more recently in *Johnson*, the Fifth Circuit again noted the limited usefulness of animal studies standing alone and noted "studies of the effects of chemicals on animals must be *carefully qualified* in order to have explanatory potential for human beings." 685 F.3d at 463 (citing *Allen*, 102 F.3d at 197) (emphasis added). Here, careful review of the Mouse Study and the case reports cited above, including the Johnston Article and the Chatham-Stephens Article, none of which is an epidemiological study, and which the Government asserts are sufficient to meet the reliability requirements of *Daubert*, lead the court to conclude that the Government has not met its burden of "carefully qualif[ying]" the Mouse Study such that it has reliable explanatory potential for human beings, and that Magistrate Judge Toliver's conclusion to the contrary was contrary to law. *See Johnson*, 685 F.3d at 463 (citing *Allen*, 102 F.3d at 197). As described by the Fifth Circuit in *Brock*:

> Epidemiology attempts to define a relationship between a disease and a factor suspected of causing it . . . . To define that relationship, the epidemiologist examines

> the general population, comparing the incidence of the disease among those people exposed to the factor in question to those not exposed. The epidemiologist then uses statistical methods and reasoning to allow her to draw a biological inference between the factor being studied and the disease's etiology.

Brock, 874 F.2d at 311. The Fifth Circuit has characterized epidemiological studies as "the most useful and conclusive type of evidence" in cases alleging injury due to exposure to a particular substance. *Id.* Defendants point out in persuasive detail why the Johnston Article and the Chatham-Stephens Article are not epidemiological studies:

> The Johnston Article, though it uses the word "epidemiologic" four times, makes clear that it is only reporting on the cases of patients who presented to Queens Medical Center in Hawaii and were diagnosed with hepatitis of unknown etiology. [Dkt. 287-6 at 3-4.] The Johnston Article did not purport to study the incidence of liver injury in the general population—indeed, it did not study the general population at all. The Johnston Article also did not include a statistically valid sample; rather, it reported on the cases of 44 individuals who had been diagnosed with hepatitis of unknown etiology, had taken a weight loss supplement within a certain period of time, and had lived in Hawaii at the time. These are the hallmarks of a case report, not an epidemiological study.
>
> The Chatham-Stephens Article fares no better: Like the Johnston Article, it reports only on the cases of patients who were diagnosed with hepatitis of unknown etiology during a certain time period and who had other, additional clinical findings. [Dkt. No. 287-8 at 2.] (The Chatham-Stephens Article studied non-Hawaii residents; it is in many senses a companion to the Johnston Article.) And like the Johnston Article, it did not purport to study the general population, nor did it include a statistically valid sample. Ironically, the Magistrate Judge has already excluded any expert testimony by the only epidemiologist who is listed as an author of the Chatham-Stephens Article—Dr. Karl Klontz—on the grounds that his testimony impermissibly relied only on a type of case reports (adverse event reports filed with the FDA). Order at 22. Neither the Johnston Article nor the Chatham-Stephens Article is an epidemiological study, nor does either "bear the hallmarks of [one]." They are case reports, plain and simple.

Defs.' Obj. 15-16 (Doc. 481).[6]

[6] In response to Defendants' objections, the Government suggests that the Johnston Article and the Chatham-Stephens Article "are more in the nature of descriptive epidemiology than analytic epidemiology," and that the Fifth Circuit has never required "pure analytic epidemiology to support animal research[.]" Gov't's Resp. 4 (Doc. 501). As described by the Government in its expert disclosures, articles that describe

The Fifth Circuit and other courts generally exclude expert testimony based on case reports. *See Black v. Food Lion, Inc.*, 171 F.3d 308, 313 (5th Cir. 1999) (case reports are "not an exercise in scientific logic but in the fallacy of post-hoc propter-hoc reasoning, which is as unacceptable in science as in law"); *Sparling v. Doyle*, 2015 WL 4528759, at *23-25 (W.D. Tex. July 27, 2015) (report and recommendations) (excluding expert opinion based on animal study and case reports), *objections overruled*, 2016 WL 236266 (W.D. Tex. Jan. 20, 2016); *Newton v. Roche Labs., Inc.*, 243 F.Supp.2d 672, 680 & n. 11 (W.D. Tex. 2002) ("The Fifth Circuit and many other courts have soundly rejected case reports as an acceptable basis for causation.") (and collecting cases).

In the final analysis, the only support for Drs. Gurley and Koturbash's conclusions on hepatoxicity of OEP-NF in human are: (1) the Mouse Study, which suffers from numerous methodological flaws highlighted by Defendants at the *Daubert* hearing; and (2) the five case reports, which courts routinely exclude.[7] Accordingly, on the face of the Government's Disclosures

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illnesses only "in terms of time, place, and person" are sometimes labeled "descriptive epidemiology." *See* Gov't's Notice of Expert Witnesses 50 (Doc. 222). The Government contrasts "descriptive epidemiology" with "analytical epidemiology," which it describes as follows: "As the name implies, statistics and other mathematical assessments are applied to ascertain specific factors associated with disease. For example, a group of ill persons, called 'cases,' may be compared to a group of well persons, 'controls,' to determine whether statistically significant differences in proportions of cases and controls exist with regard to exposures to factor[s] of interests prior to onset of illness among cases." *Id.* at 50-51. *Brock* and *Lofton*, upon which Magistrate Judge Toliver relied, refer to analytical epidemiological analysis, not "descriptive epidemiology." *See Lofton*, 2008 WL 4878066, at *4 ("Case reports lack controls and do not provide as much information as controlled epidemiological studies"); *Brock*, 874 F.2d at 313 ("[T]he epidemiologist 'uses statistical methods and reasoning to allow her to draw a biological inference between the factor being studied and the disease's etiology.'") (citation omitted). Under this precedent, and absent case law supporting its argument, the court declines the Government's invitation to label any of the five case reports as "descriptive epidemiology," or to conclude that descriptive, rather than analytical, epidemiology is sufficient in the Fifth Circuit to bolster the reliability of an animal study in the specific context of this case.

[7] The Government also urges the court to overrule Defendants' objections because Defendants proffered experts who will rely on rodent research to testify that the ingredients in Defendants' products were safe and not capable of causing liver injury. According to the Government, "It would be erroneous to allow the defendants' experts to rely on dozens of rodent studies—many or most of which contain at least one of the exact same 'flaws' that the defendants claim render the Gurley/Koturbash rodent study unreliable—while disqualifying the government's similar opinion testimony." Doc. 501 at 7.

(Doc. 222), and under Fifth Circuit law, *see, e.g.*, *Brock*, *supra*, *Allen*, *supra*, *Lofton*, *supra*, *Food Lion*, *supra*, Dr. Gurley's and Dr. Koturbash's opinions on the link between OEP-NF and liver injuries in humans, based solely on a rodent study and case reports, and lacking any epidemiological studies, are the product of on an unreliable methodology and, therefore, inadmissible under *Daubert* and Rule 702. Magistrate Judge Toliver's ruling to the contrary was contrary to law. The court, therefore, will sustain Defendants' objection, grant Defendants' motion, and exclude Dr. Gurley's and Dr. Koturbash's opinions concerning the potential link between OEP-NF and liver injuries in humans.[8]

B. Defendants' Objection to Magistrate Judge's Order with Respect to Defendants' Motions to Exclude Expert Testimony by Drs. ElSohly and Oberlies (Doc. 484)

Defendants object to Magistrate Judge Toliver's Order with respect to her denial of Defendants' Motion to Exclude the Expert Testimony of Dr. Mahmoud ElSohly and denial in part of Defendants' Motion to Exclude Expert Testimony by Nicholas Oberlies, Ph.D. Defendants'

The court has examined Defendants' expert disclosures (*see* Doc. 232) and notes that certain experts, including Dr. Rodricks, intend to rely on rodent research as part of their expert testimony. Although the Government challenged many of Defendants' proffered experts under *Daubert* and Rule 702, including Dr. Rodricks, it did not challenge them on the basis that their opinions were unreliable because they relied on rodent research. The court is mindful of its ongoing role as a gatekeeper to ensure that expert testimony meets the requirements of Rule 702 and *Daubert*. With the benefit of the court's decision, should the Government wish to challenge the admissibility of expert testimony at trial on this basis, the court will entertain its arguments at that time.

[8] Defendants also sought to exclude certain other opinions that Drs. Gurley and Koturbash intend to offer, arguing that the opinions were irrelevant and inflammatory. Among those opinions are comparisons of OEP-NF to other substances such as ephedrine, 1,3-butadiene, acetaminophen (APAP), bromobenzene, carbon tetrachloride, dimethyl nitrosamine, thioacetamide, or cyproconazolenone. Magistrate Judge Toliver denied Defendants' motion to exclude with respect to these opinions. In Defendants' objections, Defendants assert that although "Magistrate Judge clearly erred by not excluding this plainly irrelevant testimony . . . to preserve the Court's resources, Defendants shall present that argument via motion in limine." Defs.' Obj. 24 n. 30 (Doc. 481). The court's ruling today does not pertain to these additional opinions that Defendants may challenge in a motion in limine.

objection consists of the following single paragraph incorporating by reference the entirety of Defendants' briefing before Magistrate Judge Toliver:

> For the reasons set forth in Defendants' Joint Motion to Exclude the Expert Testimony of Dr. Mahmoud ElSohly and Brief in Support, Dkt #256, Defendants' Motion to Exclude the Expert Testimony of Dr. Nicholas Oberlies, Ph.D. and Brief in Support, Dkt # 252, and Defendants' respective replies in support of the ElSohly Motion and Oberlies Motion, Dkt # 314 and 323, Drs. ElSohly's and Oberlies' testimony should be excluded in their entirety.

Defs.' Obj. 1 (Doc. 484). In response, the Government argues that the court should overrule Defendants' objection, as it is a general objection and fails to comport with applicable rules. Specifically, the Government contends,

> The defendants' Objection does not specify the parts of Magistrate Judge Toliver's orders with which the defendants disagree; it does not explain how, in the defendants' view, Magistrate Judge Toliver's orders were incorrect; it does not identify the legal basis for the defendants' Objection; and it includes no brief that sets forth the defendants' arguments.

Gov't's Resp. 2 (Doc. 498). In addition, the Government argues that even were the court to consider Defendants' general objections, it should overrule the objections because Magistrate Judge Toliver's Order is not erroneous, let alone clearly erroneous. *Id.*

Federal Rule of Criminal Procedure 59(a) provides that a party may file objections to a magistrate judge's order on a nondispositive matter. "Parties filing objections must specifically identify those findings objected to. Frivolous, conclusive or general objections need not be considered by the district court." *Battle v. United States Parole Comm'n*, 834 F.2d 419, 421 (5th Cir. 1987). The Local Criminal Rules elaborate on Rule 59(a)'s requirements by instructing that objections "must be accompanied by a brief that sets forth the party's contentions of fact and/or law, and argument and authorities." L. Crim. R. 59.1(a). Failure to object to a magistrate judge's order

"waives a party's right to review" of that order, and insufficient objections "need not be considered by the district court." Fed. R. Crim. P. 59(a); *Battle*, 834 F.2d at 421.

As previously stated, Defendants' objection consists of a single paragraph incorporating by reference the entirety of Defendants' briefing before Magistrate Judge Toliver. As Defendants fail to set forth their objections in accordance with applicable rules, including Local Criminal Rule 59.1, the court declines to review Defendants' Objection and, because Magistrate Judge Toliver's rulings were orders on a nondispositive matter, allows the rulings to stand.

Even if the court considers Defendants' general objections, for the reasons that follow, the court concludes that Magistrate Judge Toliver's rulings with respect to the admissibility of the expert opinions of Drs. ElSohly and Oberlies were not clearly erroneous or contrary to law.

1. Dr. ElSohly

Magistrate Judge Toliver summarized Dr. ElSohly's credentials and anticipated testimony as follows:

> Dr. Mahmoud A. ElSohly is a research professor at The National Center for Natural Products Research and is also a Professor of Pharmaceutics and Drug Delivery at the University of Mississippi. He is additionally (1) the president and laboratory director of ElSohly Laboratories, Inc., an analytical forensic drug testing and product development laboratory, and (2) president of Phytochemical Services, Inc., a small business that serves the dietary supplement industry. Dr. ElSohly is expected to testify about the conclusions that he reached in two studies (the "2012 Study" and the "Multi-Center Study"), both of which found that DMAA was not present in geranium plants and oils.

Order 43 (citing factual record) (internal citations omitted) (Doc. 474).

In their motion to exclude Dr. ElSohly's testimony, Defendants argued that Dr. ElSohly's expected testimony regarding the absence of DMAA in geraniums was unreliable, and, therefore, inadmissible under Rule 702, because both studies were designed to avoid detection of DMAA.

Defendants asserted that, in fact, the studies did find DMAA in geraniums, and Dr. ElSohly thereafter manipulated the parameters of the studies to conceal the detection. Defendants also criticized the propriety of Dr. ElSohly's geranium sample selection and purported failure to account for obvious alternative explanations for the lack of DMAA in the studies, including the source of the plant material, the plant material sample size, and the detection limit employed. With respect to the Multi-Center Study in particular, Defendants moved to disqualify Dr. ElSohly's testimony, arguing that the study omitted the fact that the Shanghai Institute, one of the four testing laboratories, identified 2 ppb of DMAA as a constituent of geraniums and confirmed the accuracy of its tests.

Magistrate Judge Toliver rejected Defendants' motion to exclude Dr. ElSohly's testimony, noting, among other things, that Dr. ElSohly had been qualified as an expert on essentially the same topics in a civil case against USPlabs, namely, *Sparling v. Doyle*, 2015 WL 4528759 (W.D. Tex. July 27, 2015), and found that:

> Like the *Sparling* court, this Court finds Dr. ElSohly's proposed opinion testimony about the 2012 [DMAA] Study is sufficiently reliable and relevant to the case and is a proper subject for cross-examination rather than exclusion under *Daubert*. . . . Simply because Defendants do not agree with Dr. ElSohly's chosen detection limit does not mean that his testimony is unreliable and should be excluded. "Dr. ElSohly's technique has been tested, subject[ed] to peer-review and publication, with a potential rate of error, and his technique is generally accepted in the scientific community."

Order 45-46 (quoting *Sparling*, 2015 WL 4528759, at *40). More specifically with respect to Defendants' argument that Dr. ElSohly failed to account for obvious alternative explanations, Magistrate Judge Toliver again relied on *Sparling*:

> This is the same argument that the defendants in the *Sparling* case made and that the court rejected. 2015 WL 4528759, at *39-40. This Court rejects the argument for the same reasons. Although Dr. ElSohly did not test the same strains or use the same detection levels as those used in [other studies], the work Dr. ElSohly performed and his opinion based on that work is reliable because, pursuant to the

> *Daubert* factors, his technique has been tested, subjected to peer review and published on at least two occasions, and his technique is generally accepted in the scientific community. *See* Doc. 222-3 at 1-26 (Dr. ElSohly's published articles); *see also Daubert*, 509 U.S. at 592-94. Dr. ElSohly's conclusion that DMAA is not naturally occurring in geranium plants and oils is not subject to exclusion under *Daubert* simply because Defendants disagree with it. Instead they must challenge whether the methodology that he used in forming that opinion is reliable, and the Court concludes that it is. The propriety of Dr. ElSohly's geranium sample selection is a proper subject for cross-examination.

Id. at 48 (citing *Primrose Operating Co. v. National Am. Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004)).

The court's review of Magistrate Judge Toliver's rulings with respect to Dr. ElSohly's anticipated testimony reveals that she based her rulings on a plausible view of the evidence. Furthermore, she correctly concluded that the concerns raised by Defendants pertaining the admissibility of Dr. ElSohly's testimony are subjects to be explored on cross-examination and not a meritorious argument as to admissibility. *See, e.g., Primrose*, 382 F.3d at 562-63 (holding that questions relating to the bases and sources of an expert's opinion generally go to the weight of the opinion rather than its admissibility because it is "the role of the adversarial system, not the court, to highlight weak evidence"). For these reasons, and those set forth in Magistrate Judge Toliver's Order (Doc. 474), the court will **overrule** Defendants' objections to Magistrate Judge Toliver's Order denying Defendants' Motion to Exclude the Expert Testimony of Dr. Mahmoud ElSohly.

2. Dr. Oberlies

Dr. Oberlies is a chemistry professor. The Government asserts that Dr. Oberlies will testify generally about the field of pharmacognosy, how scientists are trained in this field, and some of the goals of pharmacognosy-based research.[9] According to the Government, he will present this

[9] As stated by Magistrate Judge Toliver, "pharmacognosy is defined as 'the science dealing with the sources, physical characteristics, uses, and doses of drugs.'" Order 24 note 12 (quoting

information based on his expertise and experiences training in the field, teaching in the field, lecturing in the field, and conducting research in two aspects that are cornerstones of the field, specifically the analysis of herbal medicines and drug discovery research. Gov't's Notice of Expert Testimony 60 (Doc. 222).

In moving to exclude the expert testimony of Dr. Oberlies, Defendants argued that he was unqualified to testify because he had no experience in the dietary supplement industry. Magistrate Judge Toliver rejected this argument, finding that "Dr. Oberlies is qualified to discuss how scientists perform extractions on plants and how extracts are important in the field of natural products research, the same field that USP[labs] claimed to work in. Dr. Oberlies' curriculum vitae evidences the extent of his expertise in this arena." Order 28 (citing factual sources) (Doc. 474). Magistrate Judge Toliver also found that "a review of Dr. Oberlies' curriculum vitae reveals that he has significant experience in the dietary supplement arena (albeit not in the 'industry' itself), and has conducted extensive research into herbals, botanicals and dietary supplements, and written and spoken about his findings at length." *Id.* at 24-25 (citing factual sources). The court concludes that Magistrate Judge Toliver correctly found that "Dr. Oberlies' credentials [are] sufficient to qualify him to testify regarding how a reasonable scientist would develop a biologically-active substance prior to distributing it to the public—a central issue in this case." *Id.* at 25.

In sum, a review of Magistrate Judge Toliver's ruling with respect to Dr. Oberlies reveals that she based her rulings on a plausible view of the evidence. Furthermore, she correctly concluded that the concerns raised by Defendants pertaining the admissibility of testimony by Dr. Oberlies are

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http://www.dictionary.com/browse/material-medica).

subjects to be explored on cross-examination and not meritorious arguments as to admissibility. *See, e.g., Primrose*, 382 F.3d at 562-63.

For these reasons, and those set forth by Magistrate Judge Toliver, the court will **overrule** Defendants' objections to Magistrate Judge Toliver's Order denying in part Defendants' Motion to Exclude the Expert Testimony of Dr. Oberlies.[10]

C. Defendants' Joint Objection to the Magistrate Judge's Order Denying Defendants' Motion to Exclude the Proposed Expert Testimony of Dr. Herbert Bonkovsky (Doc. 557) (filed under seal)

Defendants have filed two objections to Magistrate Judge Toliver's decision to deny their motion to exclude the expert testimony of Dr. Bonkovsky. Defendants first argue that Magistrate Judge Toliver failed to consider the purported "fictitious set of facts" and "obvious errors" underlying four articles on which Dr. Bonkovsky's testimony partially relies. Defs.' Obj. 2 (Doc. 557). Second, Defendants argue that Magistrate Judge Toliver erroneously qualified Dr. Bonkovsky's testimony at the *Daubert* hearing relating to the lack of benefits of OEP-NF. In response, the Government contends that Magistrate Judge Toliver's rulings with respect to Dr. Bonkovsky's trstimony were not "erroneous at all, let alone clearly erroneous, and the arguments raised by the [D]efendants pertain to factual disputes rather than the admissibility of Dr. Bonkovsky's testimony under *Daubert*." Gov't's Resp. 1 (Doc. 503). For the reasons that follow, the court will overrule Defendants' objections to the anticipated expert testimony of Dr. Bonkovsky.

[10] Magistrate Judge Toliver granted Defendants' motion to exclude Dr. Oberlies' opinion relating to Wilfoside KIN as irrelevant, citing the Government's lack of objection to its exclusion. *See* Order 28 (Doc. 474). In all other respects, Magistrate Judge Toliver denied Defendants' motion to exclude Dr. Oberlies' opinions.

1. Dr. Bonkovsky

Prior to addressing Defendants' specific objections, a summary of Dr. Bonkovsky's proposed testimony is required. The Government states in its disclosures that Dr. Bonkovsky will testify that in September 2013, the Hawaii Department of Health was notified of seven patients who had taken OEP-NF and been diagnosed with severe acute hepatitis and fulminant liver failure of unknown etiology. Gov't's Notice of Expert Testimony 5 (Doc. 222). According to the disclosures, Dr. Bonkovsky will further testify that, following a public health alert, 29 additional cases were discovered and 24 of those patients reported using OEP-NF prior to the onset of their illness. *Id.* at 6. Additionally, Dr. Bonkovsky proposes to testify that several doctors published a report that included observations on eight of the Hawaii outbreak patients who presented to the Queen's Medical Center ("QMC") between May and September 2013 with acute liver injury "ascribed to OEP-NF." *Id.* at 7. The report is titled "Outbreak of Severe Hepatitis Linked to Weight-Loss Supplement OxyELITE Pro," Am. J. Gastroenterol. 2014. Authors of the study include Dr. Marina Roytman of QMC's Liver Center, Dr. Linda Wong of QMC's Department of Pathology, and Dr. Naoiki Tsai of the University of Hawaii's Department of Surgery.

Dr. Bonkovsky is further expected to opine that OEP-NF "showed a strong association" with the Hawaii outbreak of serious liver injury, which occurred within a few months of the widespread marketing of that product. *Id.* at 5, 11. According to the Government, Dr. Bonkovsky will opine that (1) other etiologies of acute hepatitis "were reasonably excluded given prevailing practices in the field of hepatology" and (2) "to a reasonable degree of medical certainty, the mix of ingredients in OEP-NF was responsible for acute, severe, and sometimes fatal liver injury in patients seen not only in Hawaii, but also in several other states." *Id.* at 6, 10. Dr. Bonkovsky proposes to testify that

given all the available scientific evidence, including published, peer-reviewed research, patient medical records, and OEP-NF's "toxicological profile," the supplement should not be consumed by humans. *Id.* at 5.

2. Defendants' Objections

a. Objection One

The court turns to Defendants' first objection to Magistrate Judge Toliver's decision to deny their motion to exclude the expert testimony of Dr. Bonkovsky, namely, that she failed to consider the purported "fictitious set of facts" and "obvious errors" underlying four articles on which Dr. Bonkovsky's testimony partially relies. Defs.' Obj. 2 (Doc. 557). The articles in question are: (1) Morbidity and Mortality Weekly Report, "Notes from the Field: Acute Hepatitis and Liver Failure Following the Use of a Dietary Supplement Intended for Weight Loss or Muscle Building," CENTERS FOR DISEASE CONTROL AND PREVENTION, 62/40; 817-19 (Oct. 11, 2013); (2) Roytman et al., "Outbreak of Severe Hepatitis Linked to Weight-Loss Supplement OxyELITE Pro," Am. J. Gastroenterol. 2014; 109: 1296-1298 (the "Roytman Article"); (3) Heidemann, et al., "Severe Acute Hepatocellular Injury Attributed to OxyELITE Pro: A Case Series, Dig. Dis Sci. 2016; 61(9): 2741-48 (the "Heidemann Article"; and (4) Johnston et al., "Hepatotoxicity associated with the dietary supplement OxyELITE Pro - Hawaii, 2013," 8 Drug Testing and Analysis, Mar. 2016 (the "Johnston Article"). Dr. Bonkovsky relies on other publications as well. Doc. 222 at 13.

First, contrary to Defendants' assertion, Magistrate Judge Toliver took note of potential flaws in the data underlying the scientific record including

> (1) factual misrepresentations regarding the relative health of the affected patients and other medications and supplements they had been taking; (2) inaccurate statements that other etiologies of the patients' acute hepatitis had been excluded; (3) the use of incorrect or incomplete data; (4) incorrect application of a scoring system,

> which purposely inflated scores, to conclude that there was a causal relationship between the patients' injuries and OEP-NF; and (5) lack of clarity regarding which formulation of OEP the patients had taken.

Order 12 (Doc. 474). She concluded, however, that any "[q]uestions regarding the scientific bases of [Dr. Bonkovsky's] opinion and perceived data errors in the materials upon which he relied will doubtless affect the weight that the fact finder ascribes to that opinion, but that is best left for the jury's consideration." *Id.* at 19. It was not contrary to law for Magistrate Judge Toliver to reject Defendants' invitation to litigate the disputed facts of this case within the context of a *Daubert* motion and instead to allow Defendants to cross-examine Dr. Bonkovsky about any factual disputes at trial. As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the trier of fact's consideration. *See, e.g.*, *Primrose*, 382 F.3d at 562-63 (holding that questions relating to the bases and sources of an expert's opinion generally go to the weight of the opinion rather than its admissibility because it is "the role of the adversarial system, not the court, to highlight weak evidence.").

Additionally, although Defendants correctly assert that a trial court may examine the reliability of a proposed opinion witness's conclusions in light of the witness' sources, the *Daubert* inquiry does not involve determining the truth of every fact underlying every source relied upon by a proposed opinion witness. Magistrate Judge Toliver reasonably concluded that Dr. Bonkovsky's testimony was based on sources that were adequately reliable. As one example, Dr. Bonkovsky relied on seven published, peer-reviewed papers linking OEP-NF to liver injuries, and he reviewed dozens of patient records that also supported his conclusion. He explained at the *Daubert* hearing that such reliance was an adequate and typical method for a hepatologist to form an opinion about

the potential hepatotoxicity of a given substance. *Daubert* Tr. 75-76 (Doc. 479-12). *Daubert* and *Kumho Tire* do not require more in this context.

Further, in support of their objections pertaining to Dr. Bonkovsky, Defendants have filed over 700 pages of FOIA material that they obtained after filing their motion to exclude Dr. Bonkovsky's testimony but prior to the *Daubert* hearings. These documents include hundreds of pages of patient records that were never brought before Magistrate Jude Toliver. In the Fifth Circuit, arguments that could have been made before the magistrate judge but were not presented are waived. *Cupit v. Whitley*, 28 F.3d 532, 535 n.5 (5th Cir. 1994); *Ransom v. National City Mortg. Co.*, No. 3:13-CV-4642-L, 2014 WL 717198, at *1 (N.D. Tex. Feb. 25, 2014) (Lindsay, J.). The court rejects Defendants' request that it disturb Magistrate Judge Toliver's Order on the basis of documents they failed to present to her and arguments they did not make. Even were the court to consider the FOIA material filed by Defendants with their objections, such evidence could be a reasonable subject for cross-examination, but it has little to do with the present *Daubert* inquiry.

The court also rejects Defendants' argument that Magistrate Judge Toliver erred because she did not allow them to cross-examine Dr. Bonkovsky regarding the "obvious errors" underlying the published articles. Defs.' Obj. 1 (Doc. 557). As the Government correctly notes in response to the objections, Magistrate Judge Toliver did allow some questioning on that issue, and she did not abuse her discretion by applying clear Fifth Circuit precedent "to limit the amount of granular factual disputes covered during the *Daubert* hearing." Gov't's Resp. 6 (Doc. 503) (quoting *Pipitone*, 288 F.3d at 250) ("[W]hile exercising its role as a gate-keeper, a trial court must take care not to transform a *Daubert* hearing into a trial on the merits."). Further, as a live *Daubert* hearing is not

required, and Magistrate Judge Toliver's limits on cross-examination during the hearing were not contrary to law.

b. Objection Two

In their second objection, Defendants argue that Magistrate Judge Toliver erroneously qualified Dr. Bonkovsky's testimony at the *Daubert* hearing relating to the lack of benefits OEP-NF. In his May 9, 2018 testimony, Dr. Bonkovsky described his opinion that dietary supplements, including OEP-NF, should be "subject to prospective randomized placebo controlled trials," concluding that "OEP[NF] has never been subject to any properly done, properly respectively randomized trials to establish it is of any benefit whatever," and later concluding that the absence of prospective placebo controlled randomized trials to establish a benefit means that there is "no adequate evidence" of any benefit to OEP-NF. *Daubert* Tr. at 34:18 to 38:8 (Doc. 479-12).

According to Defendants, Dr. Bonkovsky's admission that his opinion is based solely on the absence of prospective placebo controlled randomized trials renders his testimony inadmissible, because "(1) Dr. Bonkovsky is not qualified to testify about OEP-NF's efficacy, and (2) even if he were qualified, which he is not, his testimony is irrelevant, misleading, and unfairly prejudicial." Defs.' Obj. 19 (Doc. 557). In response, after conceding that, under federal law, prospective placebo-controlled studies are not required for dietary supplements, the Government argues:

> However, this does not at all mean that Dr. Bonkovsky's testimony is inadmissible, as the defendants argue. The government has not charged the defendants with failing to perform a premarket placebo-controlled study, and nowhere has the government argued that the defendants were required by law to perform such a study. But the fact that the defendants were not required to perform a placebo-controlled study prior to marketing their product does not mean that the absence of such a study cannot help to show that the risks presented by their product outweigh the (nonexistent) benefits.

Gov't's Resp. 7 (Doc. 503). For the reasons that follow, the court overrules Defendants' second objection.

Dr. Bonkovsky's testimony on this issue is based on his opinion that there are no published scientific studies finding any benefit to consumers of OEP-NF, but there are published studies finding that consuming OEP-NF may lead potentially to liver injury. As an experienced hepatologist, Dr. Bonkovsky is qualified to opine on whether the risk of liver injury from a substance could be outweighed by a potential benefit. Magistrate Judge Toliver's decision to allow Dr. Bonkovsky to offer this testimony was well within her discretion.

Ultimately, Defendants' differences with Dr. Bonkovsky relate to numerous factual disputes to be resolved by the jury rather than questions of admissibility under *Daubert*. *Daubert* did not work a "seachange over federal evidence law[,]" and "the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system." *United States v. 14.38 Acres of Land, More or Less, Situated in Leflore Cnty.*, 80 F.3d 1074, 1078 (5th Cir. 1996) (citations omitted).

For the reasons described above, as well as those described in the Government's response to the Defendants' *Daubert* motion related to Dr. Bonkovsky (*see* Doc. 287), this court concludes that Magistrate Judge Toliver's denial of Defendants' motion to exclude the expert testimony of Dr. Bonkovsky was not clearly erroneous or contrary to law.

IV. Conclusion

For the reasons stated herein, the court **sustains** Defendants' Objection to the Magistrate Judge's Order with Respect to Defendants' Motion to Exclude Expert Testimony by Drs. Gurley, Koturbash, and Boerma (Doc. 481); **overrules** Defendants' Objection to Magistrate Judge's Order with Respect to Defendants' Motions to Exclude Expert Testimony by Drs. ElSohly and Oberlies

(Doc. 484); and **overrules** Defendants' Joint Objection to the Magistrate Judge's Order Denying Defendants' Motion to Exclude the Proposed Expert Testimony of Dr. Herbert Bonkovsky (Doc. 557).

Accordingly, the court **affirms** Magistrate Judge Toliver's Order denying Defendants' Motion to Exclude Expert Testimony by Nicholas Oberlies, Ph.D. (Doc. 252); denying Defendants' Joint Motion to Exclude the Expert Testimony of Dr. Mahmoud ElSohly (Doc. 256); and denying Defendants' Sealed Motion to Exclude Dr. Herbert Bonkovsky's Testimony (Doc. 277). With respect to Defendants' Motion to Exclude Expert Testimony by Drs. Gurley, Koturbash, and Boerma (Doc. 253), the court **affirms in part** and **rejects and reverses in part** Magistrate Judge Toliver's Order denying the motion. Specifically, the court **rejects and reverses** as contrary to law her decision to allow Dr. Gurley and Dr. Koturbash to offer testimony concerning the hepatotoxic potential of OEP-NF in rodents or the hepatotoxic potential of OEP-NF in humans based on their experiments involving rodents, and **affirms** her Order denying the motion in all other respects.[11] Drs. Gurley and Koturbash will not be permitted to offer expert testimony concerning the hepatotoxic potential of OEP-NF in rodents or the hepatotoxic potential of OEP-NF in humans based on their experiments involving rodents.

It is so ordered this 8th day of February, 2019.

Sam A. Lindsay
United States District Judge

[11] As previously stated by the court, *see supra* note 8, Defendants also sought to exclude certain other opinions that Drs. Gurley and Koturbash intend to offer, arguing that the opinions were irrelevant and inflammatory. Among those opinions are comparisons of OEP-NF to other substances such as ephedrine, 1,3-butadiene, acetaminophen (APAP), bromobenzene, carbon tetrachloride, dimethyl nitrosamine, thioacetamide, or cyproconazolenone. Magistrate Judge Toliver denied Defendants' motion to exclude with respect to these opinions.